

Operations Research Training
Curriculum for Tuberculosis Control

Facilitator Guide

Centers for Disease Control and Prevention

Center for Global Health

Division of Global HIV and Tuberculosis

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Operations Research Training Curriculum for Tuberculosis Control

Facilitator Guide

Introduction to the Course

Purpose

The purpose of this course is to train TB health care workers and public health professionals in operations (epidemiological) research to inform and improve program performance and outputs.

The overall goal of the course is to develop expertise that can contribute to measurable public health program improvements through high-quality operations research.

Target Audience

The target audience for this course is health care workers and public health program personnel who aspire to improve their programs and practices through conducting operations research.

- A participant self-assessment survey is included with the course materials to gather pre-course information about participants' backgrounds and research experience. This also serves as a pre/post-course self-evaluation tool.

Course Implementation

This training course consists of three 1-week sessions conducted 3-4 months apart with substantial individual work and one-on-one mentoring throughout the process. Upon completion, students are expected to produce a publishable manuscript for submission to a peer-reviewed journal.

- **Week 1 course duration:** 6-days **Planning a Research Study**
- **Week 2 course duration:** 6-days **Data Analysis**
- **Week 3 course duration:** 5-days **Communicating the Study to Others**

Teaching Methodology/Class Size

The curriculum includes didactic sessions, interactive activities, skill-building practicum, small group discussions, and homework assignments. A smaller class size is optimal, with the emphasis on one-on-one mentorship and small group work.

Recommended class size: 10-15 participants (2-3 per mentor)

Teaching tips for mentors leading small group work:

- Describe **your mentorship role** for the duration of the course and mentor/mentee expectations for long-distance communication and support.
- **Foster peer-to-peer support and problem solving** as part of the active-learning process, as well as an important opportunity to build a peer network.
- When breaking into small group work, consider starting each group session with brief overview to clarify next steps/instructions, share participants' progress to date, and encourage questions and problem solving.
- Small group time may also include individual work. The mentor should circulate among participants to spend 1:1 time with each mentee. Consider ending session back in the small group to answer any remaining questions and check on homework plans and progress.

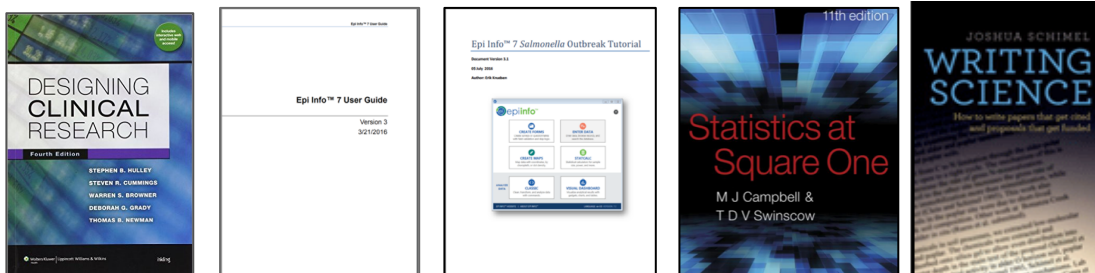
Tools and Resources

- The basic tools for conducting this course include the *Operations Research Training Curriculum for Tuberculosis Control: Facilitator's Guide* and electronic files for lecture slides, activity materials, evaluation tools, *Participant Workbooks* (which are divided into Week 1, 2 and 3 materials) and resources.



Textbooks used as resource material for the course include:

- *Designing Clinical Research, 4th edition*. 2013. By Stephen B Hulley, MD, MPH, Steven R Cummings MD, Warren S Browner MD, MPH, Deborah G Grady MD, MPH, Thomas B Newman MD MPH
- *Epi Info 7 User Guide version 3, 3/21/2016*; and *Epi Info 7 Salmonella Outbreak Tutorial v3*; the Division of Tuberculosis Elimination, Centers for Disease Control and Prevention, Atlanta, Georgia, USA; <https://www.cdc.gov/epiinfo/index.html>
- *Statistics at Square One, 11th edition*. 2009. By MJ Campbell & TDV Swinscow
- *Writing Science: How to Write Papers That Get Cited and Proposals That Get Funded* by Joshua Schimel



Course Goals and Objectives

The overall goal of the course is for TB health care workers and public health professionals to develop expertise in high-quality operations research that can contribute to measurable public health program improvements.

Goals for Week 1

At the end of Week 1, participants will be able to:

- Describe the goals of operations research
- List and apply the fundamental concepts of epidemiology and biostatistics
- Explain the key components of writing a research protocol and grant proposal
- Demonstrate the basics of designing data collection instruments using Epi Info
- Describe the essential activities required to implement operations research (addressing ethical concerns, planning for budget and timeline, development of a manual of operations, etc.)

At the end of Week 1, participants will have completed or in progress:

- A research question and associated study protocol
- A plan for implementing their studies and collecting data after completion of the course

Goals for Week 2

At the end of Week 2, participants will be able to:

- Demonstrate how to import, check and clean data to prepare it for analysis
- Conduct 1-way, 2-way, stratified, and multivariable regression analyses
- Select the most appropriate statistical tests for data inquiry
- Identify and interpret effect modification
- Recognize and control confounding
- Create tables and figures to display data

At the end of Week 2, participants will have completed or in progress:

- An analysis of their data
- Appropriate tables and figures (or draft shells/outlines) to summarize their data

Goals for Week 3

At the end of Week 3, participants will be able to:

- Prepare effective oral presentations of their study results with PowerPoints
- Write a compelling manuscript
- Write an abstract
- Revise and edit their writing

At the end of Week 3, participants will have completed or in progress:

- A final manuscript draft describing their research projects and a list of ideas for next steps for using results to impact program policy/practice

Learning Objectives for Week 1

At the end of Week 1, participants will be able to:

Overview: Operations Research + Examples

1. Define the meaning of “operations research” (OR) and describe how it differs from other types of research
2. List the 6 steps in the OR process

Developing Research Questions

1. List 5 characteristics of a good research question (FINER criteria)
2. Describe the PICO framework for developing an evidence-based inquiry

Finding and Reviewing Scientific Literature

1. Use basic Boolean operators
2. Use PubMed to conduct a literature search

Developing a Research Protocol

1. Define the purpose of a research protocol
2. Describe the 6 main components of a research protocol

Study Design

1. Describe the purpose of descriptive studies and list 3 types
2. Describe the purpose of analytic studies and list 2 main types

Epidemiology: Basic Concepts & Tools

1. Contrast the goals of descriptive and analytic epidemiology
2. Explain 2 measures of disease frequency
3. Describe 3 measures of disease association

Biostatistics: Basic Concepts & Tools

1. Contrast categorical and numerical types of measurements
2. List 5 types of graphs or charts used to visualize data
3. Explain the purpose of measuring central tendency and variation in data
4. Describe the difference between statistical and clinical significance

From “Concept to Measurement” and Sources of Bias

1. Describe 3 types of summary variables (typology, index, scale)
2. Define “precision” and “accuracy” in measurement properties
3. Explain 4 types of bias (selection, measurement, analysis, interpretation of results)

Selecting a Study Population: Sampling

1. Describe the basic principles of sampling
2. List the advantages and disadvantages of at least 3 different sampling schemes
3. Discuss types and list at least 4 potential sources of bias in sampling

Determining Sample Size and Power

1. List 4 factors that affect study power
2. Describe 3 types of error in sample size

Instrument Design: Questionnaire/Data Abstraction Tools

1. Name at least 2 examples each of qualitative and quantitative sources of primary data
2. Explain 4 elements of question formation
3. Describe 4 response categories
4. Name at least 3 examples of sources of secondary data

Epi Info: Week 1 combined sessions

1. Create variables in Epi Info
2. Design a survey and forms in Epi Info
3. Identify fields for check code
4. Write check code
5. Enter code in program editor
6. Demonstrate how to enter data using Epi Info
7. Demonstrate how to search for or delete a record

Analysis Plan

1. Describe the purposes of one-way, two-way, three-way, and multivariate analyses
2. Identify which commonly used tests best fit their research questions

Developing a Quality Management Plan and Manual of Operating Procedures

1. Describe the purpose of a quality management plan
2. Describe 6 typical content areas for a manual of operating procedures

Research Ethics

1. List 6 key principles of medical ethics
2. Describe at least 5 elements of informed consent

Learning Objectives for Week 2

At the end of Week 2, participants will be able to:

Intro: Data Cleaning, Preparation, and Analysis Plan

1. List 4 basic steps to address when cleaning data for analysis
2. Describe a basic step-wise approach for developing an analysis plan

Epi Info: Data Analysis Using the Visual Dashboard (Week 2 combined sessions)

1. Perform 1-way analyses (for categorical and continuous variables)
2. Perform 2-way analyses (for categorical and continuous variables)
3. Perform stratified analyses to explore effect modification and confounding
4. Perform multivariable regression

Basic Tools in Epidemiology, part II

1. Define, calculate, and interpret attributable risk
2. Calculate sensitivity, specificity, positive/negative predictive values, receiver operating characteristic plots
3. Interpret kappa score

Basic Tools in Biostatistics, parts IIa & IIb

1. Choose the best statistical test to create a summary data value for a variable
2. Explain the purpose of confidence intervals
3. List analytic tests best suited for use with continuous variables
4. List analytic tests best suited for use with categorical outcomes

Basic Tables & Figures

1. Demonstrate how to construct an effective table shell
2. List 3 basic types of figures, and the data most suited for each type

Stratified Analysis: Confounding and Effect Modification

1. Define confounding and list 2 ways to prevent it
2. Define effect modification, how to detect it, and how to evaluate it
3. Explain the difference between selection and information sources of bias

Linear Regression

1. Describe the concept behind linear regression
2. Describe appropriate uses of linear regression
3. Describe common pitfalls when using linear regression

Logistic Regression, parts I-IV

1. Describe appropriate uses of logistic regression and its assumptions
2. Demonstrate how to generate the probability form and logit form of a general logistic equation
3. Apply likelihood ratio test to compare models that differ by multiple variables
4. Describe steps for variable selection
5. Describe steps to assess for interactions and confounding
6. Assess interactions and confounding using dummy variables
7. Describe steps for developing predictive models

Survival Analysis

1. Describe rationale and concepts underpinning survival analysis
2. Understand, produce, and interpret Kaplan-Meier plots
3. Understand and generate Cox proportional hazards model
4. Describe how to analyze variables that do not meet the proportional hazards assumption

Learning Objectives for Week 3

At the end of Week 3, participants will be able to:

PowerPoint Presentations

1. List the 5 main components used to organize a presentation
2. Describe 4 tips to creating effective visuals in a PowerPoint presentation

Structure of Scientific Manuscripts

1. Define and follow the fundamental formula (IMRD) of a full-length article
2. Understand the significance and timeframe of the references

Writing an Abstract

1. Define the 4 main elements of an abstract
2. Describe the scientific writing process and its key stages
3. Organize and construct a structured and an unstructured abstract

Sentences

1. Identify passive voice and write in active voice
2. Identify nominalizations and convert them to verbs
3. Place the topic in the subject of the sentence and the main action in the verb

Paragraph Development

1. Identify the key components of a paragraph
2. Understand the qualities of a well-developed paragraph
3. Recognize common errors in paragraph construction and identify ways to resolve them

Introduction

1. Explain 3 structural components of an introduction as described in Schimel's *Writing Science*
2. Identify 4 main goals of a strong opening
3. Assess a manuscript introduction for likely intended audience and apply this understanding when writing an introduction
4. Review what has been done so far to solve the problem

Discussion

1. Name and describe the 2 types of story structure for the discussion section of a manuscript
2. Apply 1 of the 2 story structure options when writing their discussion
3. Identify key components that make up a strong resolution

Title Page

1. Identify key components of a title page that should meet journal-specific requirements for submission

Revising and Editing

1. Revise a manuscript to improve its meaning and consistency

Course Evaluation

Daily and Overall Course Evaluations

Electronic templates are available for course evaluation purposes. Evaluations help the course directors plan and revise material for future trainings and offer useful feedback to instructors. Both daily and overall course evaluation questions are included in the evaluation form. It is recommended that time be given for participants to fill these forms out daily to keep their responses fresh and relevant. The entire evaluation set should be printed pre-course and can be handed out and collected daily, or as a packet given the first day and collected on the last day if desired.

Faculty Feedback and De-briefing

Electronic templates are also offered for faculty feedback for each lecture/activity as well as a daily de-brief guide to assist in discussions at the end of each day. Feedback from the faculty can be rich with information to help the course evolve and improve over time. An optional "Observer Feedback Form" is also available in case a designated official "observer" is used to comment on classroom dynamics to inform future course revisions.

Pre-course Work for Students

Participants accepted into the course should be given plenty of notification prior to the course to plan for attendance and prepare their research projects.

Items to send upon acceptance to the course include:

- Formal invitation/letter of acceptance
- Brief overview of course and expectations
- Instructions regarding dates, venue, logistics (accommodations and travel information as needed), and agenda
- **Textbooks:** *Week 1: Designing Clinical Research, 4th edition (2013 Hulley)*
Week 2: Statistics at Square One, 11th edition (2009 Campbell)
Week 3: Writing Science: How to Write Papers That Get Cited and Proposals That Get Funded (2012 Schimel)
- **Electronic templates of Weeks 1, 2 and 3 participant presentation slides**
- **Pre-course student self-assessment survey**
- Instructions (see box below) on pre-course preparations

Participant pre-course instructions

Before the course:

Week 1:

- Read Chapters 1 and 2 of: *Designing Clinical Research, 4th edition (2013 Hulley)*
- Optional: Read chapters 3-7, 13-17, 19 (additional chapters covered as homework during Week 1)
- Prepare brief 5-minute presentation that describes proposed research question (using 5-slide template provided) to present on course Day 1
- Prepare 2-3 back-up research questions
- Complete and return pre-course student self-assessment survey

Week 2:

- Read *Statistics at Square One, 11th edition (2009 Campbell)*
- Prepare brief 5-minute presentation that describes proposed research question (*using 4-slide template provided*) to present on course Day 1
- Complete and return pre-course student self-assessment survey

Week 3:

- Read *Writing Science: How to Write Papers That Get Cited and Proposals That Get Funded (2012 Schimel)*
- Prepare brief 5-minute presentation that updates the status of your current research (using Week 3 template provided) to present on course Day 1
- Complete and return pre-course student self-assessment survey

Electronic Files for Course

Week 1: Course Materials (electronic files/folders)

The following materials are organized into electronic folders as follows:

1. Week 1 Course agenda (6-day template)
2. Week 1 Faculty lecture slide sets
3. Week 1 Participant pre-course materials (Week 1 pre-course homework slides template; Week 1 pre-course letter to participants template, Week 1 pre-course survey & self-assessment)
4. Week 1 Participant Materials for USB flash drive
 - a. Week 1 Participant Workbook (handout-style copy of all slide sets for note-taking)
 - b. Week 1 Handouts for activities & exercises
 - W1L16. Data Prep and Analysis Exercise
 - W1L19.1 Quality management handouts [from Division of Mycobacterium and Infectious Disease (DMID/NIH); <https://www.dmidcroms.com/CRS/QM/SitePages/Qualitymanagement.aspx>
 - Clinical Quality Management Plan Fact Sheet
 - Clinical Quality Management Plan Instructional Template
 - General Tips for Implementing Clinical Quality Management
 - W1L20.1 Manual of Operations (MOP) template and checklist
 - MOP template [from National Center for Complementary and Integrative Health (NCCIH) Clinical Research toolkit; <https://nccih.nih.gov/grants/toolbox>]
 - MOP Checklist exercise
 - W1L23.1 Create a Research Schedule Worksheet
 - c. *Epi Info 7 User Guide & Epi Info 7 Salmonella Tutorial* (electronic copies); <https://www.cdc.gov/epiinfo/index.html>; <https://www.cdc.gov/epiinfo/support/tutorials.html>
 - d. Week 1 Resources to share (optional reading material)
 - *International Roadmap for TB Research* (WHO, 2011); <http://www.stoptb.org/assets/documents/resources/publications/technical/tbresearchroadmap.pdf>
 - e. End of Week 1 Participant presentation slide template
5. Week 1 Evaluation Tools
 - Participant Daily and Final course evaluations
 - Trainer Daily Group Debrief
 - Trainer Feedback per Lecture
 - Observer Feedback

Week 2: Course Materials (electronic files/folders)

The following materials are organized into electronic folders as follows:

1. Week 2 Course agenda (6-day template)
2. Week 2 Faculty lecture slide sets
3. Week 2 Pre-course participant materials (Week 2 pre-course homework slides template; Week 2 pre-course letter to participants template, Week 2 pre-course survey & self-assessment)
4. Week 2 Participant Materials for USB flash drive
 - a. Week 2 Participant Workbook (handout-style copy of all slide sets for note-taking)
 - b. *Epi Info 7 User Guide & Epi Info 7 Salmonella Tutorial* (electronic copies);
<https://www.cdc.gov/epiinfo/index.html>; <https://www.cdc.gov/epiinfo/support/tutorials.html>
 - c. Week 2 Resources to share (optional reading material)
 - *Basic & Clinical Biostatistics, 4th edition*. (Dawson, B; Trapp, RG; 2004)
 - ActiveEpi Website: A free electronic textbook for teaching epidemiology.
<http://www.activepi.com/>
5. Week 2 Evaluation Tools
 - Participant Daily and Final course evaluations
 - Trainer Daily Group Debrief
 - Trainer Feedback per Lecture
 - Observer Feedback

Week 3: Course Materials (electronic files/folders)

The following materials are organized into electronic folders as follows:

1. Week 3 Course agenda (5-day template)
2. Week 3 Faculty lecture slide sets
3. Week 3 Pre-course participant materials (Week 3 pre-course homework slides template; Week 3 pre-course letter to participants template, Week 3 pre-course survey & self-assessment)
4. Week 3 Participant materials for USB flash drive
 - a. Week 3 Participant Workbook (handout-style copy of all slide sets for note-taking)
 - b. Week 3 Resources to share (optional reading material)
 - English Grammar Aids
 - Siegel Scientific Writing steps
5. Week 3 Evaluation Tools
 - Participant Daily and Final course evaluations
 - Trainer Daily Group Debrief
 - Trainer Feedback per Lecture
 - Observer Feedback
6. OR Course Certificate

Planning for the Training

At least 6 months prior to training:

- Convene planning committee for training to confirm agenda content and consider if revisions or updates to material are required based on target participants for specific course
- Confirm number of returning participants (or if any adjustments to participant roster)
- Confirm roles/responsibilities for planning and resources (materials, venue, catering, logistics)
- Invite and confirm faculty for training (with assignments of topics) and provide them with Facilitator's Guide and electronic copy of slides
- Secure training site (with adequate audio-video support and internet capacity); plan for enough space to allow small group breakout sessions
- Solicit participant applications (once the list is confirmed, send participant invitations/formal letter of acceptance)
- Arrange for Participant Workbooks printing (if to be done locally at course location)

At least 4-6 weeks prior to training:

- Send textbooks (if needed for any new participants) and pre-course assignments (electronic files including agenda either via email or on USB flash drive) to confirmed participants
- Confirm adequate supply of Participant Workbooks (for Day 1 distribution)
- Send pre-course participant survey; collect and consolidate responses

At least 2 weeks prior to training:

- Check that training supplies (flipchart/markers) and projector are available and working
- Confirm planned attendance of invited faculty and participants (reminder confirming agenda, location and logistics)
- Confirm small group assignments (in case of changes in faculty or participants) and share pre-course participant survey information with faculty mentors

At least 1 week prior to training:

- Prepare any printed material:
 - Course Agenda handout (fill in faculty names and adjust times as needed to weekly electronic templates provided)
 - Daily evaluation forms (participant and faculty)

Day prior to training (if possible):

- Prepare room, set-up configuration (U-shape allows for good participant interactions), ensure adequate numbers of chairs and tables, ensure table for projector and adequate electrical cords (for equipment and learners), check space/plan for small group breakouts
- Ensure laptop computer has all electronic files (lecture slides) downloaded

Morning of training:

- Set-up laptop/slide projector, flip-chart/markers/tape, power cords
- Test microphone/sound equipment
- Set-up registration area with sign-in sheet, name tags (or desktop name cards)
- Set-out handouts and Participant Workbooks
- Post Wi-Fi connectivity information
- Training team should understand who will be introducing speakers, keeping time, and assisting with materials and equipment during sessions

Checklist of Materials to Prepare

Material to give to Participants:
<p>Distribute before the course – one per participant (also see Pre-course work for students)</p> <ul style="list-style-type: none">• Week 1: <i>Designing Clinical Research, 4th edition (2013 Hulley)</i>• Week 2: <i>Statistics at Square One, 11th edition (2009 Campbell)</i>• Week 3: <i>Writing Science: How to Write Papers That Get Cited and Proposals That Get Funded (2012 Schimel)</i> <p>Distribute Day 1 of course – one per participant</p> <ul style="list-style-type: none">• <i>Participant Workbooks</i> for Week (hardcopy) and printed course agenda for week• USB flash drive with electronic folder of Participant Materials for Week (including electronic version of Participant Workbook, handouts, resources)
Material to give to Facilitators & Instructors: Distribute before course
<p>Booklets – one per facilitator/instructor</p> <ul style="list-style-type: none">• <i>Facilitator Guide</i> <p>Electronic Material</p> <ul style="list-style-type: none">• PowerPoint slides for assigned lectures• Resource folder (optional for faculty) <p>Textbook (optional for faculty)</p> <ul style="list-style-type: none">• Week 1: <i>Designing Clinical Research, 4th edition (2013 Hulley)</i>• Week 2: <i>Statistics at Square One, 11th edition (2009 Campbell)</i>• Week 3: <i>Writing Science: How to Write Papers That Get Cited and Proposals That Get Funded (2012 Schimel)</i>
Material to print for each course
<p>Print one per participant + facilitators/instructors</p> <ul style="list-style-type: none">• Course agenda for week (updated with dates/times and names of speakers) <p>Print one per participant</p> <ul style="list-style-type: none">• Participant course evaluation forms (daily and final course evaluations)• Activity handouts (varies by week, see electronic folders for handouts) <p>Print one per facilitator/instructor</p> <ul style="list-style-type: none">• Faculty debrief/evaluation forms
Equipment/materials for classroom
<p>Equipment</p> <ul style="list-style-type: none">• Laptop computer (students/faculty should bring own laptop computers if possible)• LCD slide projector and screen• USB flash drive (with PowerPoint slides for lectures and electronic resources) <p>Training/office supplies</p> <ul style="list-style-type: none">• Flipchart (2), Box of markers (1), Masking tape (1), Name tags, Sign-in sheet• Extension cords (3)• Pens/pencils and file folders/note paper (optional one per participant)

Week 1: Six-day Agenda at a glance

An electronic file of the 6-day Course Agenda is included in the course materials to be adapted for each new course and used as a printed or electronically shared agenda handout.

W1 Day 1: Research Question and Justification

Time	Lecture/Activity
8:00	Welcome and Introductions W1L1: Course Overview & Expectations
9:00	Activity: Participants introduce their research ideas (5 minutes each)
10:15	Break
10:30	W1L2: Overview: Operations Research + Examples
11:30	W1L3: Developing Research Questions
12:00	Lunch
1:00	Small group work with mentors: Participants' research questions <ul style="list-style-type: none"> • Break into assigned small groups with faculty mentors • Discuss proposed research ideas with small group
2:00	W1L4: Finding and Reviewing Scientific Literature
3:00	Small group work with mentors: Finding and reviewing scientific literature <ul style="list-style-type: none"> • Search literature and revise research question and justification as needed
	Break ad lib
4:00	Small group work with mentors: <ul style="list-style-type: none"> • Discuss revisions to research questions & justification/literature search
5:00	End Day 1 <ul style="list-style-type: none"> • Review homework for Day 2 <ol style="list-style-type: none"> 1) Participants should prepare revised research question, using FINER criteria, with brief justification to group (revise original slide presentation) 2) Review Hulley chapters: 1, 3-9, 12 • Participants complete Day 1 evaluations
5:15	Faculty Debrief

W1 Day 2: Study Design/Methods

Time	Lecture/Activity
8:00	Welcome back <ul style="list-style-type: none"> Recap Day 1 Revised research question and justification: Participants present homework
9:00	W1L5: Developing a Research Protocol <ul style="list-style-type: none"> Hulley chapter 1
9:20	W1L6: Study Design <ul style="list-style-type: none"> Hulley chapters 7-9, 12
10:20	Break
10:35	W1L7: Epidemiology: Basic Concepts & Tools <ul style="list-style-type: none"> Hulley chapters 7-9, 12
11:45	Lunch
12:45	W1L8: Biostatistics: Basic Concepts & Tools <ul style="list-style-type: none"> Hulley chapters 7-9, 12
2:00	W1L9: From “Concept to Measurement” & Sources of Bias <ul style="list-style-type: none"> Hulley chapters 4, 9
2:45	Break
3:00	W1L10: Selecting a Study Population: Sampling <ul style="list-style-type: none"> Hulley chapters 3, 5, 6
4:15	Small group work with mentors: Design study outline, add sampling & sample size <ul style="list-style-type: none"> Work to develop study design outline and methods (add sampling and sample size strategy)
5:15	End Day 2 <ul style="list-style-type: none"> Review homework for Day 3 <ol style="list-style-type: none"> Develop study design outline and methods (with sampling and sample size strategy) to present on Day 3 Review Hulley chapter: 15 Participants complete Day 2 evaluations
5:30	Faculty Debrief

W1 Day 3: Data Collection and Tools

Time	Lecture/Activity
8:00	Welcome back <ul style="list-style-type: none"> Recap Day 2 Study design and methods: Participants present homework
9:00	W1L11: Determining Sample Size and Power

9:45	W1L12: Instrument Design: Questionnaires/Data Abstraction Tools <ul style="list-style-type: none"> Hulley chapter 15
10:45	Break
11:00	Small group work with mentors: Survey instrument design <ul style="list-style-type: none"> Develop survey instruments
12:00	Lunch
1:00	W1L13: Introduction to Epi Info
1:30	W1L14: Epi Info: Creating a Questionnaire (<i>continue on Day 4</i>) <ul style="list-style-type: none"> Use Epi Info 7 User Guide
3:30	Break
3:45	Small group work with mentors: <ul style="list-style-type: none"> Use Epi Info to create questionnaires
5:00	End Day 3 <ul style="list-style-type: none"> Review homework for Day 4 <ol style="list-style-type: none"> Work on database/tools/instruments to present progress and plans to group on Day 4 No reading materials to review Participants complete Day 3 evaluations
5:15	Faculty Debrief

W1 Day 4: Analysis Plan

Time	Lecture/Activity
8:00	Welcome back <ul style="list-style-type: none"> Recap Day 3 Data collection tools/instruments: Participants present homework
9:00	W1L15: Analysis Plan
10:00	W1L16: Data Prep & Analysis Exercise: Which test(s) fit your research question? <ul style="list-style-type: none"> Use electronic file: Data Prep and Analysis Exercise
10:45	Break
11:00	Small group work with mentors: Develop your analysis plan <ul style="list-style-type: none"> Work to develop basic analysis plans (table shells)
12:00	Lunch
1:00	W1L14: Epi Info: Creating a Questionnaire (<i>continued from Day 3</i>) <ul style="list-style-type: none"> Use Epi Info 7 User Guide
	Break ad lib

3:00	W1L17: Epi Info: Enter Data <ul style="list-style-type: none"> Use Epi Info 7 User Guide
5:00	End Day 4 <ul style="list-style-type: none"> Review homework for Day 5 <ol style="list-style-type: none"> Work on basic analysis plans (table shells) to present progress and plans to group on Day 5 Read/review electronic files: Clinical Quality Plan Management Template and Example Manual of Operations Participants complete Day 4 evaluations
5:15	Faculty Debrief

W1 Day 5: Bringing the Protocol Together

Time	Lecture/Activity
8:00	Welcome back <ul style="list-style-type: none"> Recap Day 4 Basic analysis plans (table shells): Participants present homework
9:00	W1L18: Epi Info: Creating a Check Code <ul style="list-style-type: none"> Use Epi Info 7 User Guide (Session continues after lunch break)
	Break ad lib
12:00	Lunch
1:00	W1L18: Epi Info: Creating a Check Code (<i>continued</i>)
2:00	Finalizing your protocol: W1L19: Developing a Quality Management Plan <ul style="list-style-type: none"> Quality Management template and handouts (electronic file)
2:10	W1L20: Developing a Manual of Operating Procedures (MOP) <ul style="list-style-type: none"> Exercise: Fill in MOP Checklist and group discussion (electronic file) Manual of Operations Template (NCCIH)
2:30	Small group work with mentors: Finalize protocols <ul style="list-style-type: none"> Organize simple summary of research question and protocol outline for final presentation to group for Day 6
	Break ad lib
5:00	End Day 5 <ul style="list-style-type: none"> Review homework for Day 6 <ol style="list-style-type: none"> Prepare final 10-minute presentation to summarize research question and protocol outline for final presentation to group for Day 6 (Use End of Week 1 Participant presentation template) Review Hulley chapters: 14, 19 Participants complete Day 5 evaluations
5:15	Faculty Debrief

W1 Day 6: Study Plan

Time	Lecture/Activity
8:00	Welcome back <ul style="list-style-type: none"> Recap Day 5
8:15	W1L21: Research Ethics <ul style="list-style-type: none"> Hulley chapter 14
8:45	W1L22: Exercise: Create a Research Schedule Worksheet
9:30	Break
9:45	Activity: End of Week 1 Participant final presentations <ul style="list-style-type: none"> 10 min summary presentation by each participant of research question and protocol outline
12:15	Lunch
1:15	W1L23: Planning the Way Forward: Course Requirements for Week 2
1:45	Closing session <ul style="list-style-type: none"> Closing remarks Participants complete Day 6 evaluations and final evaluations
2:15	Faculty Debrief

Week 2: Six-day Agenda at a glance

An electronic file of the 6-day Course Agenda is included in the course materials to be adapted for each new course and used as a printed or electronically shared agenda handout.

W2 Day 1: Preparing for Data Analysis

Time	Lecture/Activity
8:00	Welcome and Introductions W2L1: Course Overview & Expectations
8:15	Activity: Participant presentations – give update on study status & data using Week 2 pre-course slide template: (5 minutes presentation + 5 minutes discussion each)
9:45	Break
10:00	Activity (continued): Participant presentations
11:00	Small group work with mentors: Participants meet with mentors in assigned small group to share details of study data/status
12:00	Lunch
1:00	W2L2: Intro: Data Cleaning, Preparation, and Analysis Plan

1:45	W2L3: Part 1: Epi Info: Data Analysis Using the Visual Dashboard
2:45	Break
3:00	Small group work with mentors: Participants check and clean their own data through univariate analysis; mentors assist <ul style="list-style-type: none"> • Mentors bring small group together for final Day 1 check-in
4:45	End Day 1: <ul style="list-style-type: none"> • Review homework for Day 2 <ol style="list-style-type: none"> 1) Import and clean data sets 2) Be prepared to report back on Day 2 lessons learned regarding missing data, data errors, outliers, and corrections (add on to participant presentation slides) • Participants complete Day 1 evaluations
5:00	Faculty Debrief

W2 Day 2: Epi and Biostats – Part II

Time	Lecture/Activity
8:00	Welcome back <ul style="list-style-type: none"> • Recap Day 1; Preview Day 2 • Participants discuss their experience checking and cleaning their data – missing data, data errors, outliers, corrections
9:00	W2L4: Basic Tools in Epidemiology, part II
10:15	Break
10:30	W2L3: Part 2: Epi Info: Data Analysis Using the Visual Dashboard
11:00	W2L5: Basic Tools in Biostatistics, part IIa
12:00	Lunch
1:00	W2L6: Basic Tools in Biostatistics, part IIb
1:45	Small group work with mentors: Participants carry out 2-way analysis of their own data, 2x2 tables, RxC tables, means and medians using appropriate statistical methods; mentors assist
2:45	Break
3:00	W2L7: Basic Tables and Figures
4:00	Small group work with mentors: Individual work for Tables and Graphs: Participants create Table 1 shell and data flow diagram for Figure 1; mentors assist <ul style="list-style-type: none"> • Mentors bring small group together for final Day 2 check-in
4:45	End Day 2 <ul style="list-style-type: none"> • Review homework for Day 3 <ol style="list-style-type: none"> 1) Preliminary 2-way analysis and statistical tests 2) Draft Tables 1&2, and Figure 1 (descriptive tables and figures) to present on

	<p>Day 3 (add to participant presentation slides)</p> <ul style="list-style-type: none"> Participants complete Day 2 evaluations
5:00	Faculty Debrief

W2 Day 3: Intro to Multivariable Analysis

Time	Lecture/Activity
8:00	<p>Welcome back</p> <ul style="list-style-type: none"> Recap Day 2; Preview Day 3 Participants discuss their homework, presenting their preliminary 2-way analysis, statistical tests, tables 1&2 and Figure 1 (descriptive tables and figures)
9:00	W2L8: Stratified Analysis: Confounding and Effect Modification
10:30	Break
10:45	W2L3: Part 3: Epi Info: Data Analysis Using the Visual Dashboard
11:15	Small group work with mentors: Participants begin carrying out stratified analysis of their data; mentors assist
12:00	Lunch
1:00	<p>Small group work with mentors: Carry out stratified analysis and prepare Table 3; mentors assist</p> <ul style="list-style-type: none"> Mentors bring small group together for final Day 3 check-in (before final lecture)
	Break ad lib
4:00	W2L9: Linear Regression
4:45	<p>End Day 3</p> <ul style="list-style-type: none"> Review homework for Day 4 <ul style="list-style-type: none"> 1) Continue work on data analysis, adding stratified analysis and Table 3 to present on Day 4 (add to participant presentation slides) Participants complete Day 3 evaluations
5:00	Faculty Debrief

W2 Day 4: Regression Analysis

Time	Lecture/Activity
8:00	<p>Welcome back</p> <ul style="list-style-type: none"> Recap Day 3, Preview Day 4 Participants continue presenting their study updates to the group + incorporate progress on data analysis, adding stratified analysis and Table 3 from homework (10 minute presentations + 5 minute discussions)
9:00	W2L3: Part 4: Epi Info: Data Analysis Using the Visual Dashboard

9:30	Small group work with mentors: Epi Info linear regression exercises; mentors assist
10:30	Break
10:45	W2L10: Logistic Regression, part II <ul style="list-style-type: none"> Intro to logistic regression – binary variables
11:30	W2L3: Part 5: Epi Info: Data Analysis Using the Visual Dashboard
12:30	Lunch
1:30	W2L11: Logistic Regression, part II <ul style="list-style-type: none"> Likelihood statistics and modeling strategy
2:30	W2L3: Part 6: Epi Info: Data Analysis Using the Visual Dashboard
3:00	Break
3:15	Small group work with mentors: Continue work on stratified analysis, specify variables for logistic regression <ul style="list-style-type: none"> Mentors bring small group together for final Day 4 check-in
4:45	End Day <ul style="list-style-type: none"> Review homework for Day 5 <ol style="list-style-type: none"> Continue data analysis, finish stratified analysis and begin bivariate logistic regression (add to participant presentation slides – but only need to present new information from homework; 5-minute updates only) Participants complete Day 4 evaluations
5:00	Faculty Debrief

W2 Day 5: Regression and Survival Analysis

Time	Lecture/Activity
8:00	Welcome back <ul style="list-style-type: none"> Recap Day 4, Preview Day 5 Participants present stratified analysis and bivariate regression homework (5-minute presentations + 5-minute discussions)
9:00	W2L12: Logistic Regression, part III <ul style="list-style-type: none"> Modeling categorical variables and testing model assumptions
9:45	W2L3: Part 7: Epi Info: Data Analysis Using the Visual Dashboard
10:45	Break
11:00	Small group work with mentors: Epi Info logistic regression exercise; practice with dummy variables, calculate logit plots with continuous and ordinal variables; mentors assist
11:30	W2L13: Logistic Regression, part IV <ul style="list-style-type: none"> Predictive models
12:15	Lunch

1:15	<p>Small group work with mentors: Work individually or in small groups on logistic regression, adding predictive models where appropriate; prepare final Week 2 presentations; mentors assist</p> <ul style="list-style-type: none"> • Mentors bring small group together for final Day 5 check-in (before final lectures)
3:00	Break
3:15	W2L14: Survival Analysis
4:15	W2L3: Part 8: Epi Info: Data Analysis Using the Classic Epi Info
4:45	<p>End Day 5</p> <ul style="list-style-type: none"> • Review homework for Day 6 <ul style="list-style-type: none"> 1) Prepare final 10-minute presentation to summarize data analysis and results to date <i>[Note: no uniform Week 2 final presentation slide template, participants will need to individualize presentation based on project data and analysis but should restrict to 10-minute time limit]</i> • Participants complete Day 5 evaluations
5:00	Faculty Debrief

W2 Day 6: Putting it All Together; Next Steps

Time	Lecture/Activity
8:00	<p>Welcome back</p> <ul style="list-style-type: none"> • Recap Day 5, Q&A for issues covered in Week 2; Preview Day 6
8:15	<p>Activity: End of Week 2 participant final 10-minute presentations (10 + 5 minute discussions = 15 minutes per participant) to summarize data analysis and results based study progress to date</p>
10:15	Break
10:30	Activity: Continue presentations
12:15	<p>W2L15: Planning the Way Forward: Course Requirements for Week 3</p> <ul style="list-style-type: none"> • Closing remarks • Participants complete Day 6 evaluations and final course evaluations
12:30	Lunch
1:30	Faculty Debrief

Week 3: Five-day Agenda at a glance

An electronic file of the 5-day Course Agenda is included in the course materials to be adapted for each new course and used as a printed or electronically shared agenda handout.

W3 Day 1: Presenting Your Data

Time	Lecture/Activity
8:00	Welcome and Introductions W3L1: Course Overview & Expectations
8:15	Activity: Participants present updates on status of current research projects (10-12 min each)
10:00	Break
10:15	Activity (continued): Participant Presentations
12:00	Lunch
1:00	W3L2: PowerPoint Presentations
1:45	Small group work with mentors: Meet in small groups then individually with mentor to 1) review current status of analyses and tables/figures, 2) revise PowerPoint presentation summarizing research project for Minister of Health (MOH)
	Break ad lib
4:30	End of Day 1 <ul style="list-style-type: none"> • Homework for Day 2: Finalize PowerPoint for MOH • Participants complete Day 1 evaluations
4:45	Faculty Debrief

W3 Day 2: Writing the Core Science

Time	Lecture/Activity
8:00	Welcome back <ul style="list-style-type: none"> • Recap Day 1; Preview Day 2 • Participant Presentations (continue from Day 1 as needed or volunteers to present revised research summary slides)
9:00	W3L3: Structure of Scientific Manuscripts
9:45	Small group work with mentors: Write/rewrite subjects and methods
	Break ad lib
12:00	Lunch
1:00	W3L4: Writing an Abstract

1:30	Small group work with mentors: Write/rewrite abstracts
	Break ad lib
4:30	End Day 2 <ul style="list-style-type: none"> • Review homework for Day 3: Complete abstract and methods • Participants complete Day 2 evaluations
4:45	Faculty Debrief

W3 Day 3: Writing: Nuts and Bolts

Time	Lecture/Activity
8:00	Welcome back <ul style="list-style-type: none"> • Recap Day 2; Preview Day 3 • Participants present updates/revisions to their written drafts
9:00	W3L5: Writing Well, part 1: Sentences
9:30	Small group work with mentors: Write/rewrite results
	Break ad lib
12:00	Lunch
1:00	W3L6: Writing Well, part 2: Paragraph Development
1:30	Small group work with mentors: Write/rewrite introduction
	Break ad lib
4:30	End Day 3 <ul style="list-style-type: none"> • Review homework for Day 4: Work on introduction and manuscript • Participants complete Day 3 evaluations
4:45	Faculty Debrief

W3 Day 4: Writing: Telling Your Story

Time	Lecture/Activity
8:00	Welcome back <ul style="list-style-type: none"> • Recap Day 3; Preview Day 4 • Participants present updates/revisions to their written drafts
9:00	W3L7: Telling a Compelling Story, part 1: Introduction
9:30	Small groups with mentors: Write/rewrite introduction
	Break ad lib
	Small groups with mentors: Write/rewrite introduction (<i>continued</i>)

12:00	Lunch
1:00	W3L8: Telling a Compelling Story, part 2: Discussion
1:30	Small groups with mentors: Write/rewrite discussion
	Break ad lib
4:30	End Day 4 <ul style="list-style-type: none"> • Review homework for Day 5: Continue work on manuscript • Participants complete Day 4 evaluations
4:45	Faculty Debrief

W3 Day 5: Review and Revise Your Work

Time	Lecture/Activity
8:00	Welcome back <ul style="list-style-type: none"> • Recap Day 4; Preview Day 5 • Participants present updates/revisions to their written drafts
9:00	W3L9: Title Page
9:30	W3L10: Revising and Editing
10:00	Small groups with mentors: Revise 1 st draft, generate 2 nd draft
	Break ad lib
12:00	Lunch
1:00	Small groups with mentors: Participants finalize 2 nd draft
	Break ad lib
3:30	Final course QA/discussion
4:00	Closing graduation <ul style="list-style-type: none"> • Final course certificates (Week 3) • Participants complete Day 5 evaluations and final course evaluations
4:15	Faculty Debrief

Participant Presentation Slide Templates for Weeks 1-3

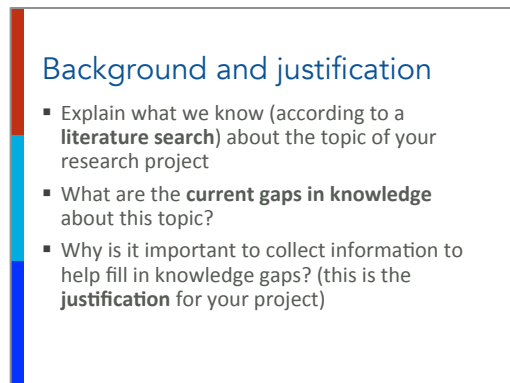
Electronic files for the participant presentation slide templates are included in the Participant Material folders for each week. The basic templates are included here for easy reference by course faculty.

Week 1: Participant Pre-course Homework slide template

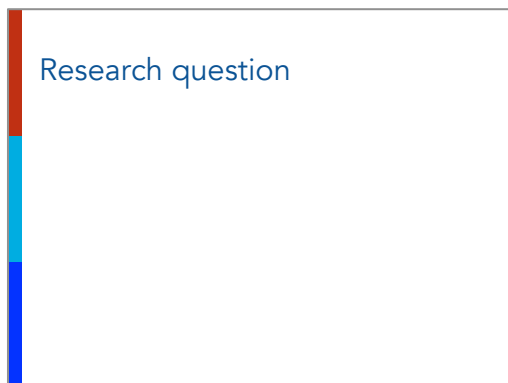
Slide 1



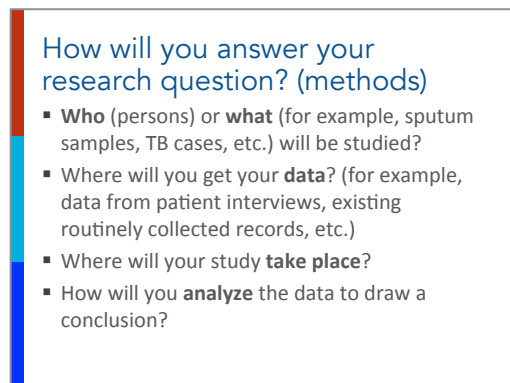
Slide 2



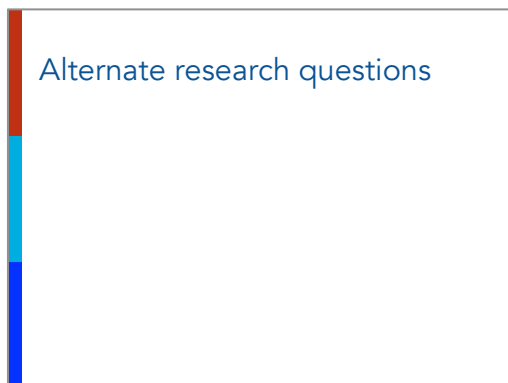
Slide 3



Slide 4



Slide 5




Week 1: Participant End of Week 1 slide template

Slide 1

Title of your OR Project

Name
Organization where you work
Country



Slide 2

Background

- Describe the problem in a few bullet points

Slide 3

Background

- Refer to scientific evidence to help explain the burden of the problem and rationale for the study
- Cite a few (~2-3) reports and published research from a literature review

Slide 4

Research question

- Write your research question

Slide 5

Methodology

- Study design
- Study population
- Sources of information

Slide 6

Methodology

- Data collection
 - What data will you collect
 - How will you collect the data
 - Who will collect the data
 - Training

Slide 7

Analysis plan

- Outcome(s)
- Exposure(s)
- Other variables measured and analyzed

Slide 8

Ethical issues

- What ethical issues do you have to take into consideration

Slide 9

Dissemination and action plan

- Describe how you are planning to share your results or what you are planning to do with the findings

Week 2: Participant Pre-course Homework slide template

Slide 1

Week 2:
[Your Project Title]

Your name
Your employer



Slide 2

Research question

Slide 3

Methods

- Give outline of study methods/structure

Slide 4

Study progress

- Give brief update on status of your study
- Include any preliminary data (or explain status of data/enrollment to date)

Week 3: Participant Pre-course Homework slide template

Slide 1

Week 3:
[Your Project Title]

Your name
Your employer



Slide 2

Study progress

- Give brief update on the status of your study using format provided in this template
- If study is ongoing, include any preliminary data (or explain status of data/enrollment to date)

Slide 3

Background

- [Brief description of why it was important to do your study]

Slide 4

Research question/Objectives

- [State your research question and study objectives]

Slide 5

Methods

- [Study design, study population, what you measured and how you analyzed your data]

Slide 6

Results

- [Subject characteristics, key findings from your study]

Slide 7

Limitations

- [Limitations of your study]

Slide 8

Conclusions and implications

- [Emphasize your main findings and state potential implications your work may have]